REMARKS

This amendment is submitted in response to the Official Action mailed November 26, 2008. Claims 1-32 are pending. Claim 1 is amended to more particularly point out and distinctly claim the invention. In particular, claim 1 is amended to delete "cellulose acetate trimaletate," which is a typographical error, and replace the recitation of "Eudragit poly acrylic acid, Eudragit S, and Eudragit L," with the generic description of the polymers: "anionic polymers of methacrylic acid that dissolve at a pH from 5.5 to 7." Support for this amendment is found at, for example, page 11, lines 7-10 of the originally-filed application and the manufacturer's website for Eudragit S and Eudragit L: http://www.pharma-polymere.de/pharmapolymers/en/eudragit/entericcoatings/. No new matter is added. In view of the above claim amendments and the following remarks, reconsideration by the Examiner and allowance of the application is respectfully requested.

Furthermore, the amendment places the claims in better form for consideration on appeal, for which entry is permitted under 37 C.F.R. §1.116(b)(2). The amendment also does not alter the scope of the claims in a manner that would require a new search or burdensome work on the part of the Examiner. Accordingly, the Examiner is requested to telephone the undersigned at the below-listed telephone number should there be any issues remaining to be resolved. In the event the Examiner does not consider the application to be in condition for allowance, entry of the amendments for consideration on appeal is respectfully requested.

Turning to the Official Action, claims 1-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action notes that "claim 1 recites the broad recitation 'Eudragit poly acrylic acid,' and the claim also recites 'Eudragit S and Eudragit L' which are narrower statements of the range/limitation." (Office Action, page 10). The Office Action further states that "Claim 1 contains the trademark/trade name 'Eudragit®'." As noted above, claim 1 is amended to replace the recitation of "Eudragit poly acrylic acid, Eudragit S, and Eudragit L," with the generic description of the polymers: "anionic polymers of methacrylic acid that dissolve at a pH from 5.5 to 7." Therefore, this rejection is respectfully traversed.

Claims 1-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,137,733 to Noda et al. in view of U.S. Patent No. 5,580,578 to Oshlack et al. Applicants' claimed formulation is a multiparticulate bisoprolol formulation wherein each particle comprises a core of bisoprolol or a pharmaceutically acceptable salt thereof surrounded by a polymeric coating comprising at least one enteric polymer coating material selected from cellulose acetate phthalate, hydroxyl propyl methylcellulose phthalate, polyvinyl acetate phthalate, anionic polymers of methacrylic acid that dissolve at a pH from 5.5 to 7, polyvinyl acetaldiethylamino acetate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate and shellac. All of the enteric polymers recited in claim 1 exhibit pH-dependent dissolution profiles. (See Exhibits A-C).

Noda et al. does not disclose or suggest a bisoprolol formulation that includes at least one enteric polymer coating material selected from the group recited in claim 1. Noda et al. is limited to pH-independent coatings and makes clear that its formulations are designed for dissolution that is independent of the pH. See, for example, the Abstract ("dissolution pattern irrespective of the pH of a dissolution medium") and the Background of the Invention ("An object of this invention . . . and the rate of the dissolution of the medicinal compound does not depend on the pH of a medium for the dissolution"). The polymers that Noda et al. exemplifies are recognized in the art as pH-independent. Also, the experiments described in Noda et al. show a formulation that exhibits a pH-independent drug release profile. Clearly, pH-independence is at the very heart of the Noda et al. teaching.

The Office Action indicates that "acrylic polymers are taught [by Noda et al.] at col. 2, lines 40-59 and include Eudragit RS as well as a combination of Eudragit RS and RL." (Office Action, page 6). However, the acrylic polymers recited by Noda et al. at col. 2, lines 40-59 are polymers that include a trimethylammoniumethyl group in the molecule. (See Noda et al. at col. 2, line 43). The present claims do not recite acrylic polymers that include a trimethylammoniumethyl group. According to the manufacturer's website for Eudragit RS and RL (http://www.pharma-polymere.de/pharmapolymers/en/eudragit/sustainedreleaseformulations/),

methacrylate copolymers with trimethyl-ammonioethylmethacrylate as a functional group exhibit pH-independent swelling.

The present invention, on the other hand, relies on the use of a polymer system for which the dissolution depends on the pH of the medium. Applicants' claimed invention is specifically formulated to exhibit a release of bisoprolol that is affected by the pH of the medium. This is very clearly different from the formulation disclosed by Noda et al. Replacing the pH-independent coatings of Noda et al. with the pH-dependent coatings claimed in the present application would change the principle of operation of the Noda et al. pH-independent formulations. According to M.P.E.P. 2143.01(VI), "If the proposed modification . . . of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

Oshlack et al. does not cure the deficiencies of Noda et al. The Office Action relies on Oshlack et al. for its purported disclosure of "a controlled release formulation wherein a barrier layer is incorporated between the medicinal core and the acrylic coating layer." (Office Action, page 9). Even assuming Oshlack et al. does disclose such a barrier, this does not guide one of skill in the art to a pH-dependent polymer system as presently claimed. Thus, the combination of Noda et al. with Oshlack et al. does not teach or suggest the presently claimed invention. Therefore, this rejection is respectfully traversed.

CONCLUSION

In view of the above claim amendments and the foregoing remarks, this application is believed to be in condition for allowance. Reconsideration is respectfully requested. However, the Examiner is requested to telephone the undersigned if there are any remaining issues in this application to be resolved.

Finally, if there are any additional charges in connection with this response, the Examiner is authorized to charge Applicant's deposit account number 50-1943 therefor.

Respectfully submitted,

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